REMARKS

I. Status of the Claims

Claims 21-29 and 31-39 are pending in the application. Claims 21 and 32 have been amended. Claims 38-39 are newly added.

Claims 21 and 32 have been amended to reflect the currently preferred embodiment of the invention. Support for the amendments is found throughout the specification of U.S. Prov. App. No. 60/345,637, the application to which the instant application claims priority, in particular, at page 3, lines 11-13; and page 9, lines 10-12.

Support for newly added claims 38-39 is found throughout the specification of U.S. Prov. App. No. 60/345,637, the application to which the instant application claims priority, in particular, at page 6, lines 24 and page 37, lines 17-22.

As no new matter has been added by these amendments, Applicants respectfully request that the amendments be entered.

II. Restriction Requirement and IDS

Applicants acknowledge that the restriction requirement has been made final and that claims 21-29 and 31-37 and SEQ ID NO: 508 as recited in the claim 36 have been examined on the merits.

Applicants apologize for the delay in submitting the information disclosure statement. An IDS is filed herewith.

III. Priority

The Office has alleged that the disclosure of the prior-filed application, provisional application 60/345,637, fails to provide adequate written description support for the claims directed to a method of identifying an anti-cancer agent or a method of screening a candidate agent for anti-

cancer activity. More specifically, the Office alleges that the term "anti-cancer" cannot be found anywhere in provisional application 60/345,637. As the pending claims no longer recite the term "anti-cancer," Applicants respectfully assert that the Office's contention regarding priority is moot.

IV. Rejection of Claims 21-29, 31-34 and 37 under 35 USC §103(a)

Claims 21-29, 31-34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/21994 ('994). In particular, the Office Action states that the '994 teaches VMP1 antagonists and that the '994 also teaches drug screening assays which may be used to identify compounds that have suitable binding affinity to VMP1. The Office further asserts that there are no differences between the prior art and the claims at issue and that one of skill would have been motivated to devise a method for identifying an anti-cancer agent that modulates a biological activity of a gene product differentially expressed in a cancerous cell as compared to a normal cell comprising contacting a candidate anti-cancer agent with a cell that expresses DKFZ since the '994 teaches that the end-products of such a method can be used to treat and prevent disorders associated with the expression of VMP1, including breast cancer. Finally, the Office asserts that one of skill would have had a reasonable expectation of success for the claimed method because the '994 teaches that such a method was routine and well-known in the art at the time of filing.

Applicants respectfully traverse the rejection and its supporting remarks. In order to establish a *prima facie* case for obviousness, three criteria must be met: 1) the cited references must teach or suggest all elements of the claimed invention; 2) there must be a reason or motivation to modify or combine the references; and 3) there must be a reasonable expectation that such a combination would work.

The instant claims relate to DKFZ protein. The specification indicates that DKFZ is also known as VMP1, or *vacuole* membrane protein 1. The '994 application relates to the "Human *Vesicle* Membrane Protein-Like Proteins" known as VMP1, VMP2, and VMP3. Despite the similar names, these are distinct proteins, as there is no significant sequence similarity between the two proteins. As such, the cited reference fails to teach that detecting a difference in biological

activity and expression level of DFKZ expressed by a cell can be used in methods of identifying cancer therapeutic agents.

Therefore, for at least the reason that the cited references fail to teach or suggest that limitations of the claims, the Office has failed to establish a *prima facie* case for obviousness. Withdrawal of the rejection is respectfully requested.

V. Rejection of Claims 35 and 36 under 35 USC §103(a)

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/21994 ('994) as applied to claims 21-29 and 31-34 and 37 above, and further in view of Dusetti et al. and US Pat. No. 6,844,325. Applicants respectfully traverse this rejection and its supporting remarks.

As an initial matter, Applicants note that Dusetti et al. is not available as prior art. Dusetti et al. was published in the January 18, 2002 issue of the Biochemical and Biophysical Research Communications. As discussed in further detail above, the instant application has a priority date of January 8, 2002.

Further, even if Dusetti et al. were available as art, it would fail to support a *prima facie* case for obviousness. Claims 35 and 36 are dependent on claim 31[1], which specifies that the candidate agent is an DKFZ antisense polynucleotide which inhibits DKFZ gene expression by at least 90%. Claim 35 further specifies that the DKFZ antisense polynucleotide comprise a nucleotide sequence comprising at least 12 contiguous nucleotides of SEQ ID NO: 513, or complement thereof. Claim 36 further specifies that the DKFZ antisense polynucleotide comprise a nucleotide sequence selected from the group consisting of SEQ ID NO: 508 and SEQ ID NO: 510. As discussed above, the '994 fails to teach or suggest all elements of the claimed invention. Dusetti fails to remedy this deficiency, as it relates to the cloning and characterization of the VMP1 protein

[1] Applicants presume that the Office's reference to claims 35 and 36 being dependent on claim 32 was a typographical error.

as a stress-induced gene that promotes formation of intracellular vacuoles followed by cell death when overexpressed. No mention is made of any relation between the VMP1 protein and cancer.

The '325 also fails to remedy the deficiency of the '994 application. The '325 relates primarily to various clones over-expressed in breast cancer tumor tissue, none of which include DKFZ. The '325 thus fails to teach that detecting a difference in biological activity and expression level of DFKZ expressed by a cell can be used in methods of identifying cancer therapeutic agents.

For at least the above reasons, the Office has failed to establish a *prima facie* case for obviousness of claims 35 and 36. Withdrawal of the rejection is respectfully requested.

VI. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection

with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **223002105200**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

In addition, please direct all further communications in this application to:

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